adverse effects profile of the medication. The most support was registered for the optimal scenario (halt disease progression, no adverse effects).

PND49

MIGRAINE: PRESCRIBING PATTERNS IN A SOUTH AFRICAN PRIMARY CARE PATIENT POPULATION

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OBJECTIVES: Migraine affects 8% to 14% of the population in Western countries. It affects primarily the young adult population and is responsible for many lost working days each year since it affects primarily the economically active sector of the community. The primary aim of the study was to determine the prescribing patterns and cost of drugs for migraine in a primary care patient population. **METHODS**: A retrospective drug utilisation consumption study was conducted. Data were obtained from a South African private health care group. The database consisted of all central nervous system medicine for 2008. **RESULTS**: A total of 22102 patients (71.05% females) received 43144 items for migraine a cost of R3622552 (average cost of R83.96 per item). The average age of patients was 44.90 (SD = 13.83) years, with 70.76% of patients between 30 and 59 years of age. The chi-square test was used to detect prescribing differences between female and male patients in different age groups ($chi^2 = 212.31$; d.f. = 6; $p < 0.0001$). Differences were observed in prescribing to female and male patients. Patients were prescribed an average of 1.95 items for migraine over the year. The Lorenz curve was used to illustrate skewness in prescribing. Clonidine was the most frequently prescribed active ingredient (46.15%), followed by cyclizine (29.62%). The agents for the prophylaxis of migraine (clonidine, flunarizine and pizotifen) accounted for 50.48% of prescribing frequency and 29.04% of cost. The selective $5HT_1$-receptor agonists (triptans) accounted for 18.94% of prescribing frequency and 53.54% of cost. Rizatriptan was the most frequently prescribed triptan. **CONCLUSIONS**: The findings were generally in agreement with two other South African studies, although differences were observed. A lower prescribing rate for triptans has been observed. Qualitative studies on migraine are needed in South Africa to determine its impact on the quality of life of patients.

SYSTEMIC DISORDERS/CONDITIONS – Clinical Outcomes Studies

PSY1

SYSTEMATIC REVIEW OF THE EFFICACY AND SAFETY OF PHARMACOTHERAPIES USED IN CHRONIC LOW BACK PAIN

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OBJECTIVES: Chronic low back pain (CLBP) is a major cause of disability, affecting mainly working-age adults and imposing a large economic burden on society. Since no consensus exists regarding standard of care for this condition, the objective of this study was to systematically review the efficacy and safety of pharmacotherapies used for CLBP. **METHODS**: A systematic literature review was conducted through July/August 2008, searching MEDLINE, EMBASE, and bibliographic details of relevant studies. Prospective trials and observational studies were included if they assessed pharmacotherapies in adults with CLBP and were written in English. Efficacy endpoints included: pain relief, pain interference with activities, individual's functioning and response to treatment. Adverse event (AE) rates and withdrawal rates due to AEs were also assessed. Extensive study heterogeneity prohibited quantitative synthesis. **RESULTS**: From 773 citations screened, 65 studies (published between 1982 and 2008) were selected, of which 54 were randomized controlled trials. The efficacy measures most consistently reported across studies included the visual analogue scale (VAS) and the Roland Morris Disability Questionnaire (RMDQ). Non-steroidal anti-inflammatory drugs (NSAIDs), weak and strong opioids, several antidepressants (clomipramine, mianserin, and duloxetine titrated based on patient response and tolerability), the anticonvulsant topiramate, and certain transdermal medications (transdermal fentanyl and lidocaine patches) significantly reduced pain intensity. The effectiveness of injections (i.e., glucose and lidocaine) and other antidepressants (paroxetine, trazodone or bupropion) was uncertain. Regarding patient functioning, significant improvements were observed for NSAIDs, opioids and duloxetine, but not for local injections. The magnitude of effect of these endpoints ranged from small to moderate, depending on the pharmacotherapy assessed. **CONCLUSIONS**: NSAIDs, opioids, some antidepressants, an anticonvulsant and certain transdermal medications seemed to significantly reduce pain intensity in CLBP, while inconclusive results were obtained for other antidepressants and local injections. Overall, the study findings were consistent with current guideline recommendations from Europe and US.

PSY2

EVALUATING ADVERSE EVENT RISK WITH PROPOXYPHENE: ARE THERE DIFFERENCES BETWEEN ELDERLY VERSUS YOUNGER PATIENTS?

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OBJECTIVES: Propoxyphene is among the most commonly prescribed opioid analgesic in the elderly. However, many guidelines, including the American Geriatric Society and Beer's List of Potentially Inappropriate Medications, recommend restricting its use in that age group. These guidelines are based on expert opinions with limited empirical evidence. The objective of this study was to evaluate whether there were differences in adverse event reporting for propoxyphene by age group using a large post-marketing safety surveillance data. **METHODS**: Analysis was conducted using the 2005–2008 Adverse Event Reporting System (AERS) data in the US, which was developed to support the FDA's post-marketing safety surveillance program for all approved products. Adverse events reported with propoxyphene as primary, secondary or interacting drug were categorized into central nervous system (CNS) and gastrointestinal (GI) adverse events (AEs). Logistic regressions were used to assess the risk of CNS and GI adverse events (AEs) among the elderly (age > = 65) and younger patients (age < 65) controlling for gender and those reporting the AEs. Proportional reporting ratios (PRR) for the propoxyphene-AE combination were also computed for the elderly and younger patients. **RESULTS**: In the period 2005–2008, a total of 2497 propoxyphene-AE combinations were reported, 261 were CNS-related and 127 were GI-related. In multivariate analysis, controlling for gender and those reporting the AEs, no significant differences were observed in the risk of CNS-related AEs (Odds ratio: 0.827; 95% CI: 0.619–1.105; p = 0.199) or GI-related AEs (Odds ratio: 1.216; 95% CI: 0.832–1.778; p = 0.313) among elderly versus young patients. Among the elderly, the PRR for propoxyphene-CNS AEs was 0.795 and the PRR for propoxyphene-GI AEs was 0.596. These were similar to the PRRs among younger patients, which were 0.700 and 0.439, respectively. **CONCLUSIONS**: Using a voluntary post-marketing surveillance database, the study found no differences in the extent of CNS AEs and GI AEs reported with propoxyphene among elderly patients versus younger patients.

PSY3

DETERMINING THE COST OF OBESITY AND ITS MAJOR COMORBIDITIES FROM A COMMERCIAL CLAIMS DATABASE

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OBJECTIVES: To determine payments made by commercial health care providers for adults diagnosed with obesity, and those who are comorbid with any combination of the following chronic conditions: diabetes mellitus (DM), hypertension, depression, and/or congestive heart failure (CHF). **METHODS**: We utilized a 10% random sampling from a commercial claims and encounters database (n = 12,416,190). The study population (n = 50,717) was limited to those who: 1) were adults age 18–64; 2) filed a claim between 2006–2007; 3) had at least one inpatient visit, one outpatient visit, or one emergency department visit; and; 4) had been given a primary or secondary diagnosis of obesity. Persons were identified and categorized if they had one or more comorbid diagnoses (DM, hypertension, depression, and/or CHF) in addition to obesity. After adjusting for age and gender, we calculated the mean total net expenditures (in $US 2007) for each combination of comorbid conditions. All calculations were performed in Stata. **RESULTS**: Among those diagnosed with obesity, the mean net expenditures for services were $1799 per patient. Persons diagnosed with obesity and other comorbidities observed an increase in total net expenditures. Obesity and hypertension observed the highest increase among single comorbidities at $4298. For persons with obesity and two other comorbidities, DM and depression was the highest at $14,364. The most expensive condition in the study sample was obesity, DM, hypertension and depression at $14,843. All results were statistically significant at the 95% confidence level. **CONCLUSIONS**: Compared to the average medical claim, persons diagnosed with obesity along with other common chronic conditions experience significant increases in health care costs. These costs are often driven higher by the time spent as inpatients. In many cases, obesity may be the cause of other chronic conditions that result in these high costs. Thus, by controlling and reducing the prevalence of obesity, we may see significant decreases in health care expenditures.

PSY4

CHALLENGES IN USING THE LITERATURE TO ESTIMATE THE OUTCOMES OF CURRENT RISK STRATIFICATION METHODS IN ADULT PATIENTS WITH PRIMARY ACUTE MYELOID LEUKEMIA

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OBJECTIVES: Treatment of patients with acute myeloid leukemia (AML) is based upon stratification into risk (prognosis) groups. New diagnostic methods are in development to improve this stratification. Economic evaluations of these methods require knowledge of what happens when the current stratification methods are used. We examined whether the literature can provide valid estimates for the outcomes of complete remission rates for patients with primary AML aged 16–60 years. **METHODS**: A systematic literature review was performed using Pubmed and Embase. Inclusion criteria were: ≥100 AML patients and detailed outcomes per risk group (favorable, intermediate, unfavorable). Excluded were: Phase I/II studies, studies not containing any patients aged 16–60 years or with primary AML. We compared various study characteristics such as patient population, treatment given, risk group definitions and complete remission (CR) rates as outcome. A chi-square test for homogeneity of CR rates was performed. **RESULTS**: Twelve studies fulfilled the eligibility criteria. Great variation was found between study populations. While treatment varied between the studies, all patients received cytarabine and an anthracycline. Definitions of risk groups varied greatly except for the favorable risk group. There was no homogeneity in overall CR rate (range: 52–85% $p < 0.001$). After excluding studies with many patients other than the target population, heterogeneity between the remaining studies decreased (N = 7, p = 0.083). CR rates were homogeneous in the favorable group (p = 0.223), but heterogeneous in the intermediate and unfavorable groups (p = 0.044 and p = 0.096 respectively). **CONCLUSIONS**: Differences in patient population and

risk group definitions lead to heterogeneity in CR rates. Only a small number of studies will provide valid estimates of the CR rates in patients with primary AML aged 16–60 years. However, this restriction may reduce the reliability of the estimates, because the estimates will be based on fewer patients. This will thereby increase the uncertainty around the ICER of new methods.

PSY5

A RETROSPECTIVE CHART REVIEW OF THE TREATMENT OF PHENYLKETONURIA IN THE UK AND ASSOCIATED CLINICAL AND HEALTH OUTCOMES

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OBJECTIVES: To determine the proportion of phenylketonuria (PKU) patients managed successfully using current treatment strategies and to highlight a particular group(s) of PKU patients who may be uncontrolled by current treatment. **METHODS**: This is a non-interventional, retrospective, observational study. To date 4 UK sites have enrolled into the chart review. Information on patients with PKU or tetrahydrobiopterin (BH_4) deficiency was collected over a five year period (2004–2008). Data was collated on demographics, diagnosis, number of uncontrolled episodes, interventions made during an uncontrolled episode and the length of time phenylalanine (Phe) levels were above the target level. An uncontrolled episode is defined as three or more consecutive Phe levels above the National Society for Phenylketonuria (NSPKU) guideline. Interventions can include dietary advice, health care professional phone calls, clinic visits, counselling/psychological support, addition or change in use of supplements, social care visits, and hospital admission. Data was analysed to explore the treatment of PKU in practice, the accompanying Phe levels and other health and clinical outcomes. **RESULTS**: Recruitment is being completed. This information will be reported as a full dataset in the poster. Thus far data has been collected for 102 patients across 3 centres (50% male). The age range of patients reviewed was 6–60 years. A total of 93% of patients had a diagnosis of PKU, 0% BH4 deficiency and 7% unknown. The average number of uncontrolled episodes per patient per year was 1. An average of 7 interventions were made during each episode. The average length of the episode was 176 days. **CONCLUSIONS**: There is lack of published data on the management of PKU in clinical practice. This study provides an analysis of current treatment of PKU in clinical practice and its effectiveness on clinical and health outcomes. The majority of PKU patients within this study had well-controlled Phe levels, however a number may benefit from additional treatment.

PSY6

EFFECT OF MODERATE-INTENSITY EXERCISE TRAINING AND DIET ON BODY COMPOSITION AND EXERCISE CAPACITY IN OBESE CHILDREN

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OBJECTIVES: Childhood obesity is a serious health problem favouring the early development of insulin resistance, type-2 diabetes mellitus and cardiovascular diseases. Our aim was to investigate multidisciplinary weight-control program applying exercise training at maximal fat oxidation (FATmax) zone and diet in three different duration on body composition and physical fitness of overweight children. **METHODS**: Thirty overweight pupils (BMI > percentile 90%) of three different elementary schools (age: 11.7 +/– 1.9) was included. Body composition was determined by bioelectric impedance method. Graded exercise test (Jaeger Oxycon Pro) was used to determine whole-body peak fat oxidation by indirect calorimeter. Training heart rate interval was determined by as +/– 10% of FATmax. Physical exercises were prescribed by the physiotherapist. Exercise training was performed 2 times /week in the school using heart rate monitor under the control of the games master. The training periods were 56, 101 and 146 days. Dietary proposal was given for the parents of children by the dietetics. **RESULTS**: At the end of the weight-control program percentage of fat mass decreased (35.7 +/– 4.5 vs. 33.0 +/– 5.5%; $p < 0.001$), muscle mass increased (22.8 +/– 4.6 vs. 24.4 +/– 5.2 kg; $p < 0.001$). VO_2max increased at the longest training period only (1841 +/– 620 vs. 2011 +/– 642 ml; $p = 0.043$). **CONCLUSIONS**: Moderate intensity exercise training and diet resulted in favourable changes in the body composition in a short term whereas the significant improvement of VO_2max was started only after 5 months training period.

PSY7

EVALUATION OF MEASURES UNDERTAKEN TO ENHANCE THE ROBUSTNESS OF THE FABRY OUTCOME SURVEY (FOS)

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OBJECTIVES: To assess the impact of measures undertaken to improve data capture in the Fabry Outcome Survey (FOS). A physician-directed, multinational database established in 2001, FOS aims to advance the understanding and management of Fabry disease, a rare lysosomal storage disorder caused by deficiency of alfa-galactosidase A. **METHODS**: This initiative, supported by Shire HGT is driven by physicians in the management of Fabry disease. In 2006, additional measures were introduced to enhance the robustness of data capture: 1) a core dataset was developed for assessing disease progression and therapy response; 2) focus was directed at those participating centers with ≥20 patients enrolled in FOS; and 3) research associates were employed to monitor data capture and quality. Random samples (25%) of all enrolled patients were selected from the years 2004 and 2007, before and after the changes, respectively. The completeness of data capture was determined for 10 core variables in each year. **RESULTS**: Data capture was analyzed for 197 of the 815 patients enrolled in FOS in 2004 and for 404 of the 1616 patients enrolled in 2007. Increases in data capture occurred for 9 of 10 core variables; the exception was patient weights, which were unchanged at 90% for both years. For key variables, the increases were: signs and symptoms, from 66% to 83%; serum creatinine, from 89% to 91%; left ventricular mass, from 48% to 55%; NHYA score, from 84% to 87%. In addition, the proportion of females enrolled increased from 48% to 54%. **CONCLUSIONS**: Focused efforts on improving data completeness and quality in FOS have been successful, optimizing the value of the database. Regular, accurate data collection and audit will increase the quality of FOS data and lead to an improved understanding of the management of Fabry disease.

PSY8

TAPENTADOL EXTENDED RELEASE (ER) FOR CHRONIC LOW BACK PAIN: RESULTS OF EUROQOL-5 DIMENSION (EQ-5D) AND SHORT FORM-36 (SF-36) HEALTH STATUS QUESTIONNAIRES

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OBJECTIVES: To evaluate the efficacy and safety of tapentadol ER in patients with moderate-to-severe chronic low back pain. Health status was evaluated using SF-36 and EQ-5D questionnaires. **METHODS**: Patients received controlled, adjustable twice-daily doses of tapentadol ER (100–250 mg), oxycodone HCl controlled release (CR; 20–50 mg), or placebo over a 12-week maintenance period, preceded by a 3-week titration period. Patients completed the EQ-5D and SF-36 at baseline and at specified visits. EQ-5D evaluates mobility, self-care, usual activities, pain/discomfort, and anxiety/depression; SF-36 evaluates physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health dimensions. **RESULTS**: Of 981 patients randomized, 958 were evaluated for efficacy. Compared with placebo, improvements from baseline to endpoint in the SF-36 physical component summary score were significantly greater with tapentadol ER (least-squares mean difference vs placebo [95% CI], 2.3[1.02,3.58], $P < 0.001$) and oxycodone CR (2.3[1.02,3.56], $P < 0.001$). Both active treatment groups were associated with significant improvements over placebo in role-physical (tapentadol ER, 9.9[4.21,15.49]; oxycodone CR, 9.4[3.83,15.05]; both $P < 0.001$) and bodily pain (tapentadol ER, 5.5[2.44,8.55]; oxycodone CR, 6.3[3.23,9.29]; both $P < 0.001$). Additionally, tapentadol ER was associated with significantly better outcomes versus placebo in physical functioning (4.1[0.85,7.33], $P = 0.013$) and vitality (3.2[0.41,6.01], $P = 0.025$), while oxycodone CR was not significantly different from placebo on these parameters (physical functioning, 2.6[–0.66,5.77], $P = 0.119$; vitality, 0.8[–1.99,3.58], $P = 0.576$). For both active treatment groups, changes from baseline in general health, social functioning, role-emotional, mental health, and mental health summary score did not differ significantly from placebo (all $P > 0.285$). Compared with placebo, the EQ-5D health status index at endpoint improved significantly compared with baseline with tapentadol ER (0.05[0.01,0.09], $P = 0.020$) and oxycodone CR (0.05[0.01,0.09], $P = 0.019$). Incidences of treatment-emergent adverse events were placebo, 59.6%; tapentadol ER, 75.5%; and oxycodone CR, 84.8%. **CONCLUSIONS**: Tapentadol ER (100–250 mg bid) significantly improved physical and overall health status in patients with moderate-to-severe chronic low back pain.

PSY9

ADHERENCE TO DULOXETINE THERAPY AND HEALTH CARE COSTS AMONG PATIENTS WITH FIBROMYALGIA

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OBJECTIVES: To examine predictors of adherence to duloxetine therapy and assess the association between adherence and health care costs among working-age patients with fibromyalgia. **METHODS**: This study analyzed medical and pharmacy records for commercially-insured patients aged 18–64 diagnosed with fibromyalgia who initiated duloxetine between January 1, 2006 and December 31, 2006. The date of first duloxetine prescription filled was defined as the index date. Initiation of treatment was defined as no pill coverage for duloxetine over the prior 90 days. All patients included had at least 30 days supply of duloxetine in the 12 months post-index period. Patients with diabetes peripheral neuropathic pain or depression in the 12 months pre-index period were excluded. Two study cohorts were constructed based on adherence level to duloxetine (high adherence = medication possession ratio of = 0.8). Predictors of high adherence were examined via logistic regression. Multivariate regression models were performed to examine the association between adherence and health care costs, controlling for demographics, clinical characteristics, and prior health care costs. **RESULTS**: A total of 4869 fibromyalgia patients were identified, with a mean age of 50 years and 88% female. Approximately 68% of duloxetine patients had low adherence over the 12 months follow-up period. Higher average daily dose was associated with high adherence (reference group = 30 mg; Odds Ratio = 3.03, 2.40, and 3.74 for 31–59 mg, 60 mg, and > 60 mg, respectively; all $p < 0.05$). Controlling for differences